

Touching lives, improving life. *P&G*[™]

Designing Safety Into Products

A continuous analysis of alternatives

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September 15, 2011



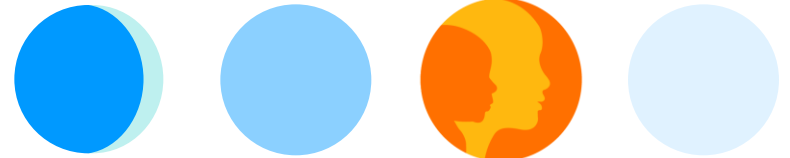
P&G

Product Safety — A Business Must

Company Policy

“Ensure that our products, packaging and operations are safe for our employees, consumers and the environment and comply with all applicable regulations.”

- P&G Worldwide Business Conduct Manual



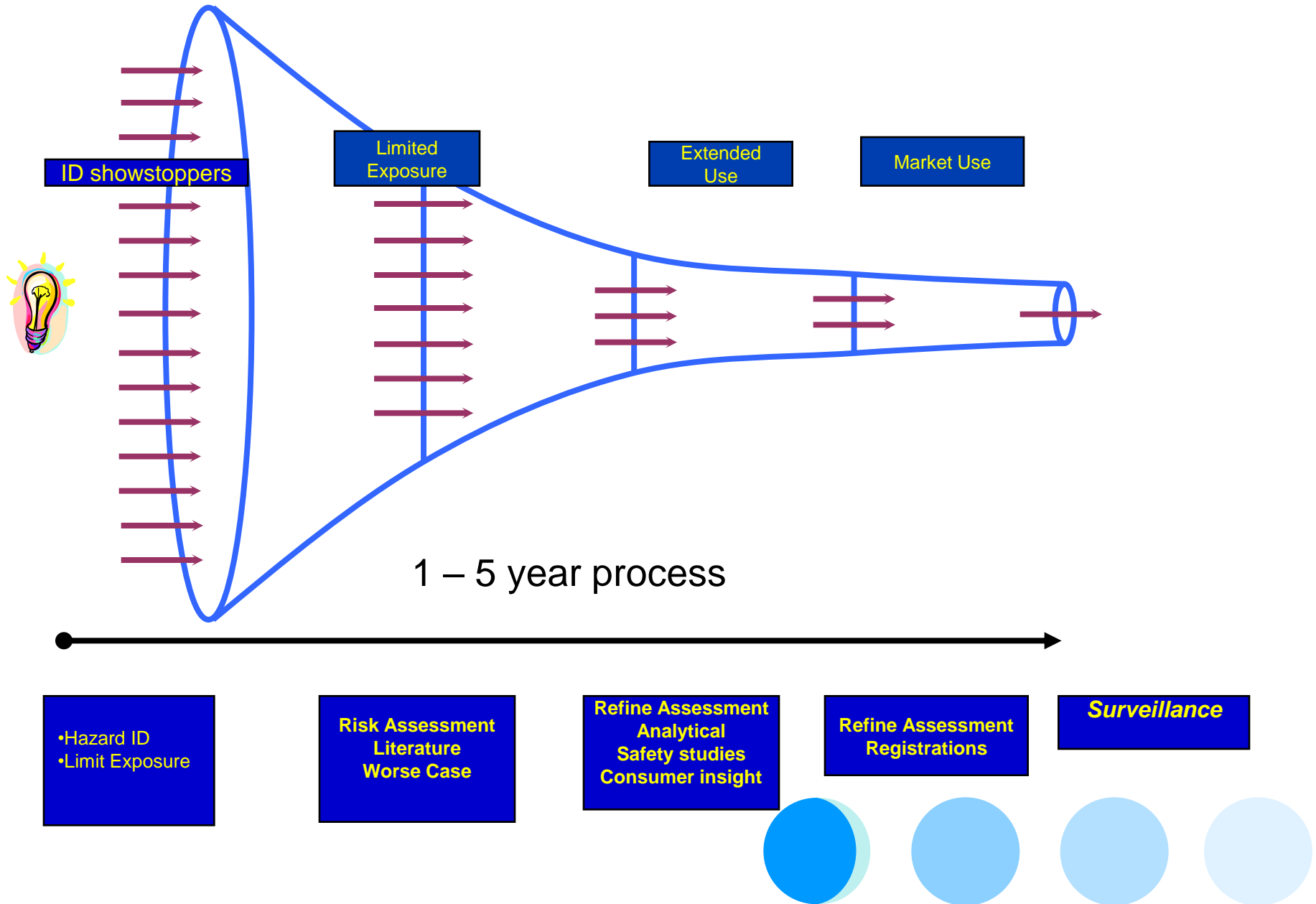
Safety Capability

- 700 People world wide
- 18 Countries
- 120 PhDs, MDs, DVMs
- Research Program driven by our safety assessment needs –
- 2,600 publications from P&G Safety Scientists

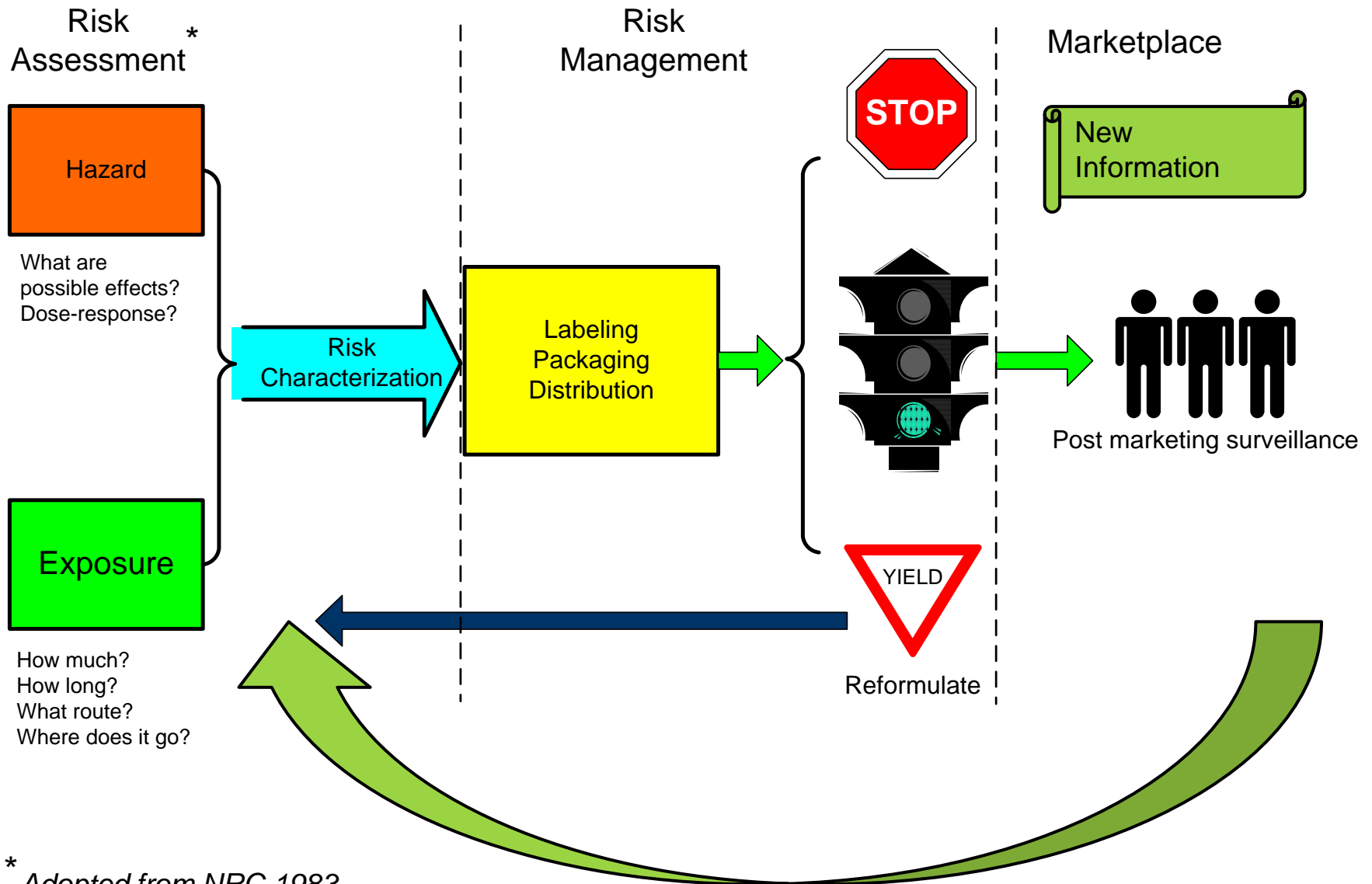




Design Safety In – *Right from the start*



Product Development Process

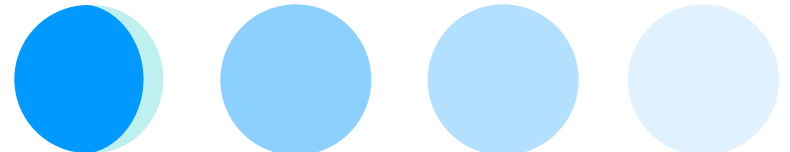


* Adopted from NRC 1983

Science Based Safety Assessments

Principle

- An ingredient is not safe or unsafe
- It's the use and exposure of an ingredient that can be judged as safe or unsafe



Goal of Safety Assessment

Amount used < amount that can cause harm

Exposure

- Route
- Duration
- Amount
- Other sources
- Unintended exposures

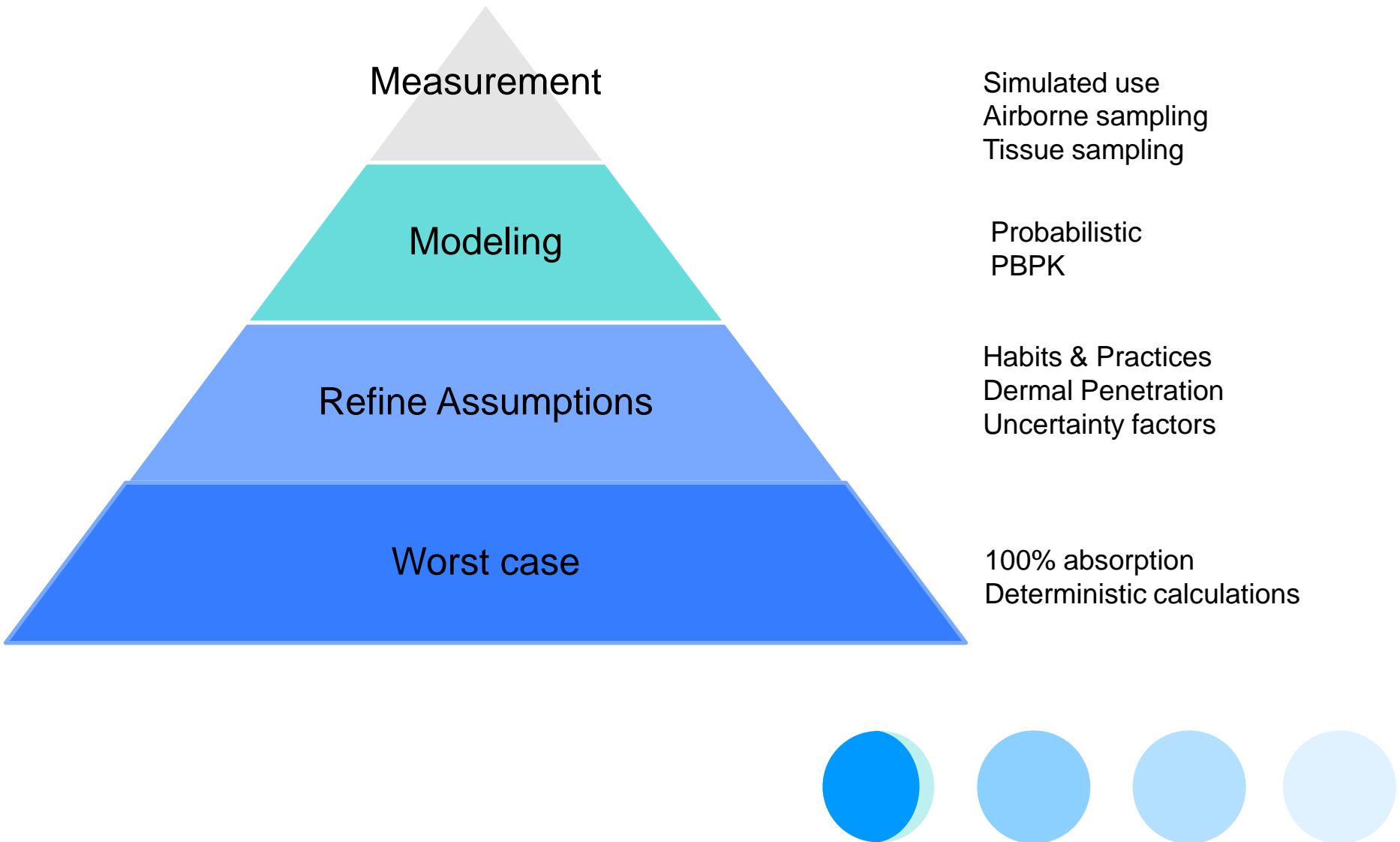
Hazard & Dose Response

- Endpoints
- Dose/route
- Susceptible populations

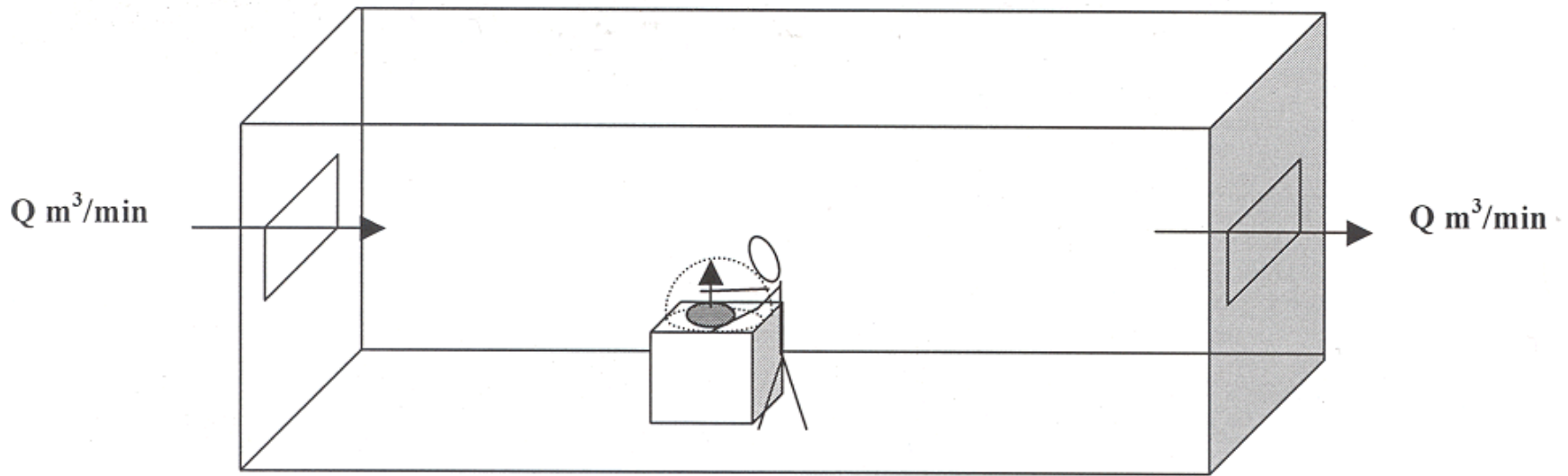
Safety Decisions

$$\text{MOS} = \frac{B_{RV}}{E_{xp}} \quad \text{Or} \quad \frac{PNEC}{PEC}$$

Exposure Assessment



Exposure Example - Inhalation



Simple

$$C_{\text{avg}} = M/V$$

Assumes no air exchange (Q)
All material released at once
Instant mixing
M is mass
V is volume

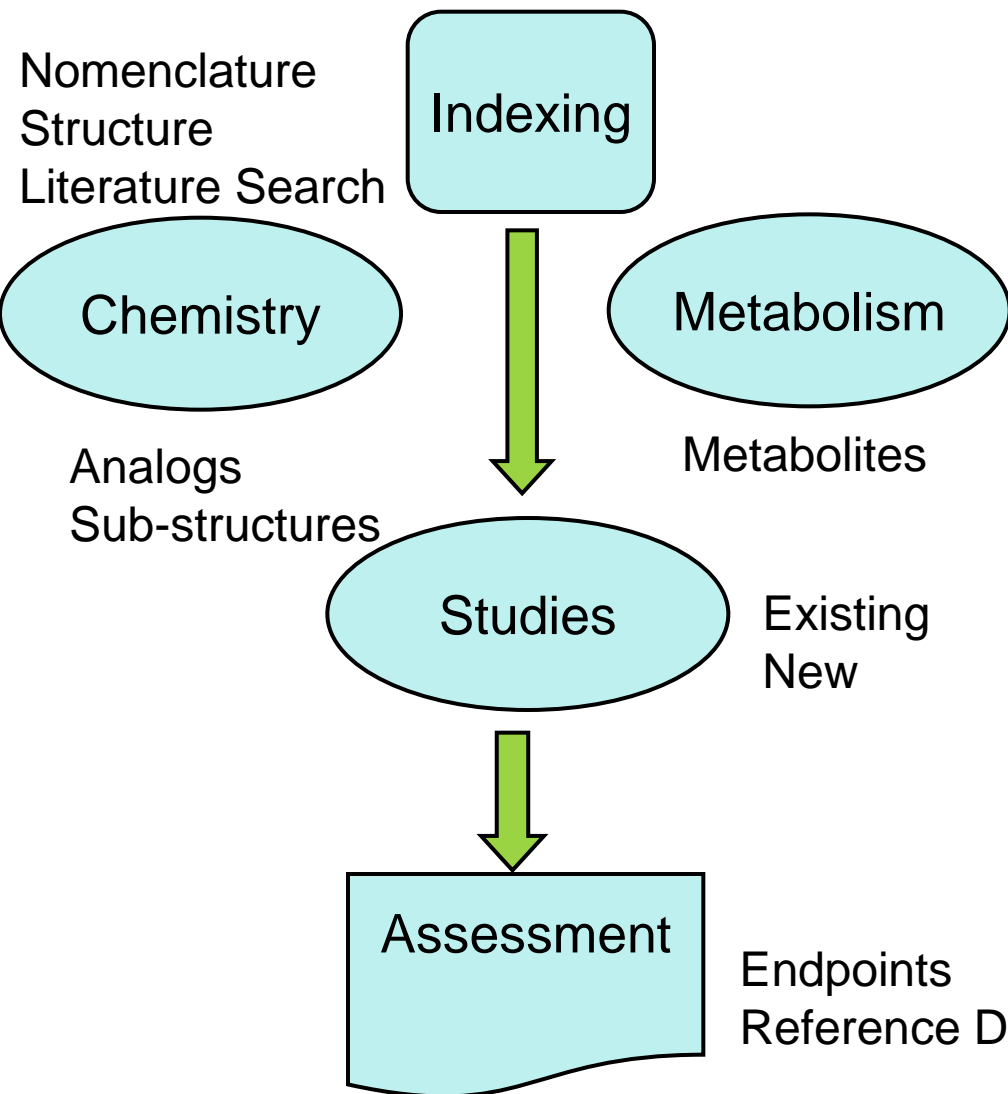
Complex

$$C_{\text{avg}} = \frac{G}{Q^2} \left(Q + \frac{V}{t} \left(e^{-\frac{Qt}{V}} - 1 \right) \right)$$

Assumes air exchange rate (Q)
Material is released at a rate of G
t is time of exposure



Hazard and Dose Response Assessment



Internal and External
Sources of information

Structure and
substructure searching

Chemical Reference File

CRF#: 1737 CAS#: 3302-10-1 ALT/DEL CAS#: PG #: 168987

Chemical Name: Hexanoic acid, 3,5,5-trimethyl- Manage Chemical Structure

Synonym(s): 3,5,5-Trimethylcaproic acid 3,5,5-Trimethylhexanoic acid Manage Synonyms

Chemical Class: Manage Chemical Class

Created By: Fitzgerald Date Created: 18-Jun-2010

Home Page Format for Printing Edit Save Attach Cross-Ref Manage Cross-Ref

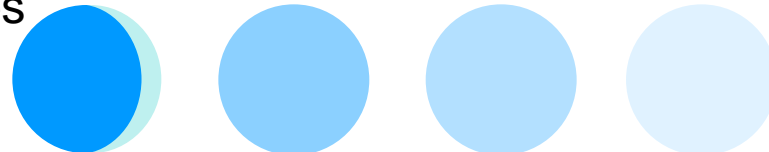
CRF Help Manage Alt CAS CRF - Cross-Ref View Comments

Requests: Manage Requests Change CRF

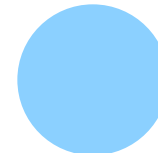
REQ#	Type	Endpoints	Detail	Requester	Submit Date	Status
2857	SAR-OTH	GENO-CARC, SK-SENS, DEV-REP, ACUTE, SUBCHR, METAB	N/A	lu.x.2	23-JUN-2010	Complete

Assessments: Manage Assessments

REQ#	Type	Endpoints	Detail	Owner	Status Date	Status
2857	SAR	DEV-REP	N/A	broening.hw	10-SEP-2010	Complete
2857	SAR	GENO-CARC	N/A	stitttholt.ca	20-JUL-2010	Complete
2857	SAR	SK-SENS	N/A	deconinck.er	15-JUL-2010	Complete
2857	SAR	ACUTE	N/A	li.n.7	12-JUL-2010	Complete
2857	SAR	SUBCHR	N/A	stuard.sb	07-JUL-2010	Complete
2857	OTH	METAB	N/A	wu.s.3	29-JUN-2010	Complete



Special populations



Example – Compact Liquid Laundry

Safety Assessment

136 Publications
56 Supplier studies
33 Internal studies

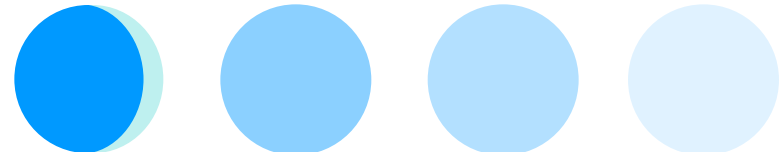


MOS 165 - 2,500

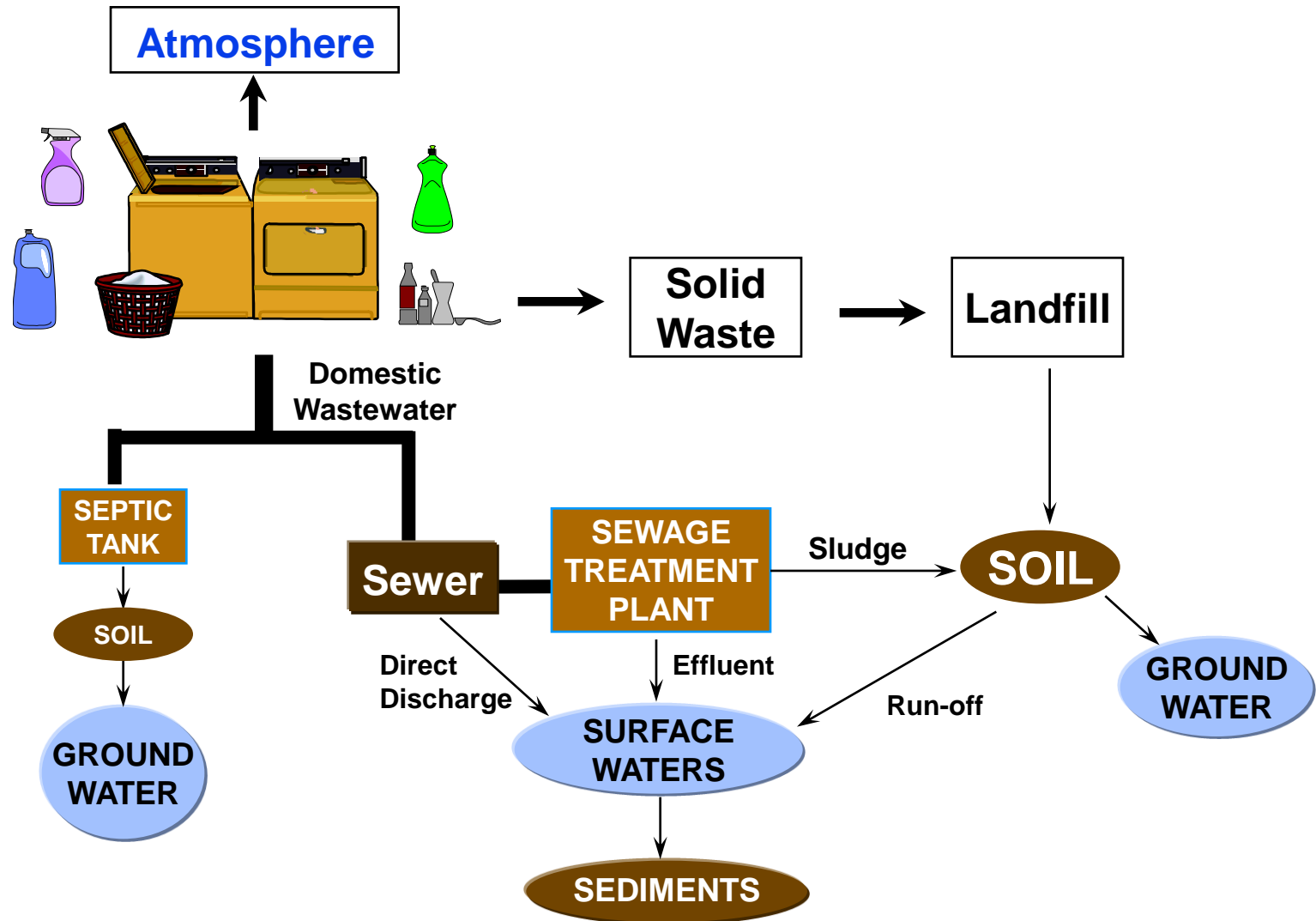
20 Billion wash loads/year

Formula Example: Premium Compact Liquid Laundry Detergent

Alcholethoxy sulfate	20.1%	Diquaternium ethoxy sulfate	1.6%
Linear alkylbenzene sulfonate	2.7%	Polyethylene glycol-polyvinyl acetate	0.4%
Alkyl sulfate	6.5%	Polyethyleneimine propoxyethoxylate	1.0%
Laureth-9	0.8%	Diethylenetriamine pentaacetic acid	0.4%
Citric acid	3.8%	Disodium diaminostilbene disulfonate	0.01%
C12-18 fatty acids	2.0%	Ethanol	2.6%
Protease (stock)	1.5%	Propylene Glycol	4.6%
Amylase (stock)	0.3%	Diethylene Glycol	3.0%
Mannanase (stock)	0.1%	Polyethylene glycol	0.2%
Pectate Lyase (stock)	0.1%	Monoethanolamine	2.7%
Xyloglucanase (stock)	0.3%	Dye	0.01%
Borax	3.0%	Perfume	0.5%
Calcium formate	0.1%	NaOH to pH 8.3	
Sodium formate	0.1%	Water to 100%	



Environmental Pathways & Exposure



How We Assess Environmental Effects

QSAR Predictions

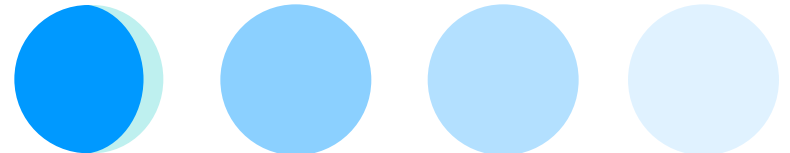
- mathematical models

Single Species Testing (Acute & Chronic)

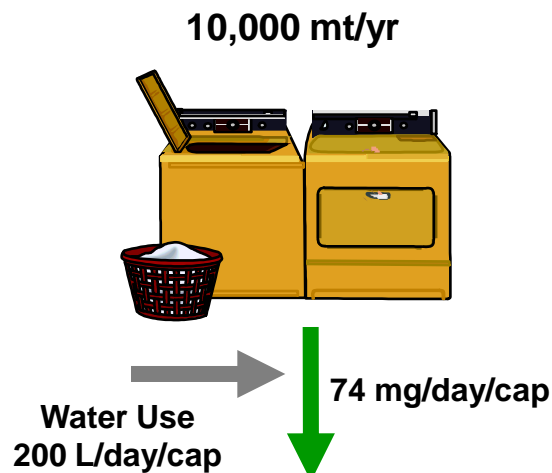
- Terrestrial (Agricultural Sustainability)
 - Higher Plants and Earthworms
- Aquatic Environment
 - Algae, Invertebrates & Fish

Mesocosm Testing

- Ponds Experimental Stream Facility



Example – Anionic Surfactant



Wastewater
372 $\mu\text{g/L}$

99%
Removal

Sewage
Treatment Plant

Effluent
3.72 $\mu\text{g/L}$

Stream Flow

River Water **PEC**
0.37 $\mu\text{g/L}$

Risk Ratio = PEC/PNEC

= 0.37 $\mu\text{g/L}$ / 64 $\mu\text{g/L}$

= 0.006

MOS >170 fold

Life Cycle Assessment (LCA) in product innovation

Covers a variety of evaluation factors

Energy consumption

Water consumption

Use of resources

Solid waste

Global warming

Emissions into air

Ozone depletion

Human toxicity

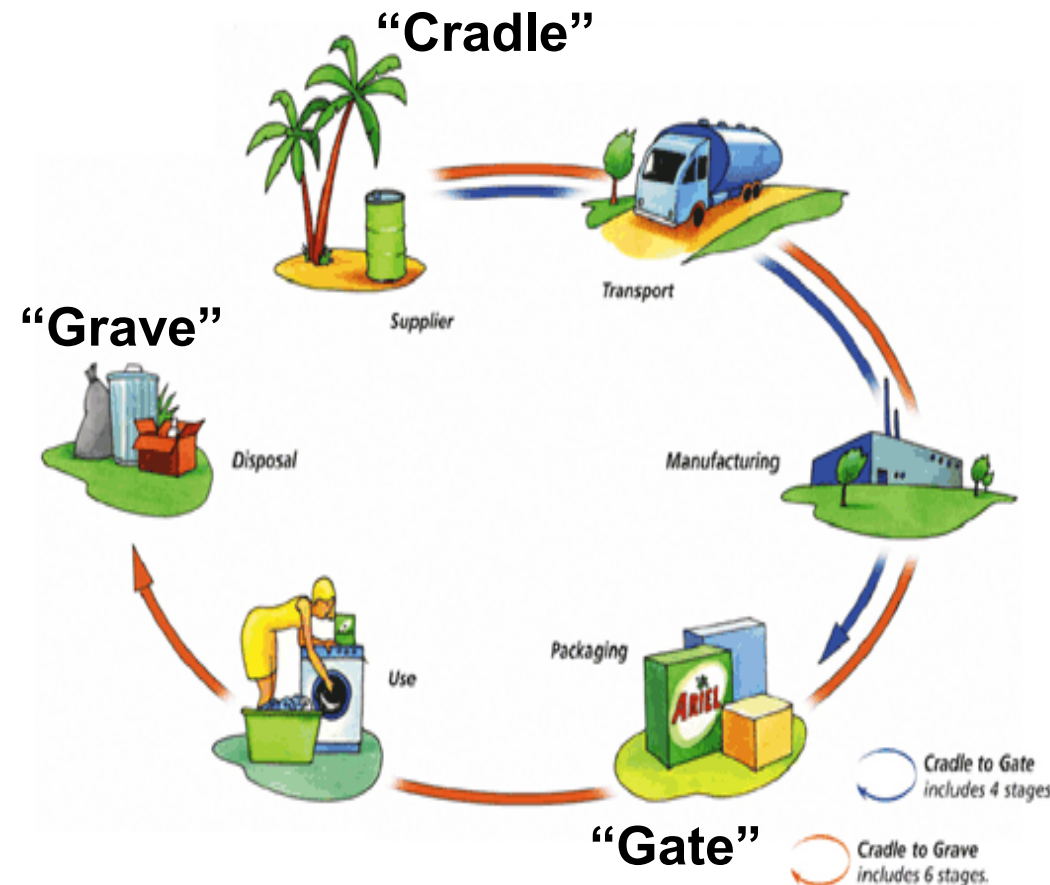
Summer smog

Emissions into water

Acidification

Eutrophication

Aquatic ecotoxicity



Importance of “Informed Substitution”

Decision Elements

- Technological feasibility?
- Does it improve health and environmental safety?
- How does it impact cost, performance, economic/social considerations?
- Is it sustainable?
- What are the trade offs?



Increasing Transparency—Sharing P&G Science and Safety Information

- P&G Product Safety

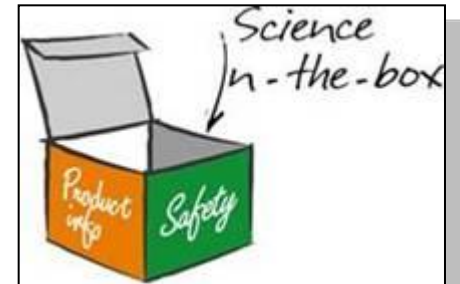


Product Safety

- <http://www.pgproductsafety.com/productsafety/index.shtml>

- Laundry and cleaning products technology

- www.scienceinthebox.com



- Beauty

- www.pgbeautyscience.com

P&G beauty & grooming

